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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,309	01/23/2004	Wayne H. Kaesemeyer	126625.00801	6530

7590 12/21/2006

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EXAMINER	
CRANE, LAWRENCE E	
ART UNIT	**PAPER NUMBER**
1623	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/21/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,309	KAESEMEYER, WAYNE H.	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 23, 2004 (preliminary amdt.)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/1/04, 3/27/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The Abstract of the Disclosure is objected to because is does not meet the requirement of the MPEP for US application. Correction is required. See MPEP 608.01(b).

Applicant is respectfully requested to update the abstract to correspond to the subject matter of the claims.

The instant disclosure fails to include an up-to-date "Cross-References to Related Applications." See 37 C.F.R. §1.78 and MPEP at §201.11. Applicant is respectfully requested to amend as appropriate the first paragraph of the disclosure.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1600, Art Unit 1623.

No claims have been cancelled, no claims have been amended, the disclosure has been amended at page 1, and no new claims have been added as per the preliminary amendment filed January 23, 2004. Two Information Disclosure Statements (2 IDSs) filed October 1, 2004 and March 27, 2006 have been received with all but one cited references and made of record. See individual IDS's for references not made of record for lack of complete bibliographic information.

Claims **1-30** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claims **1-30** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant disclosure does not include any specific embodiments or related experimental data in support of the claimed invention and therefore is deemed to lack an adequate written description of the claimed invention. The only mention of the pharmacological equivalence of

L-arginine and L-citrulline occurs at page 4, lines 15-19, and there are no exemplifications in support of this assertion. For example, there are no comparative exemplifications wherein the administration of mixtures of an Hmg-CoA reductase inhibitor and L-arginine, and mixtures of an Hmg-CoA reductase inhibitor L-citrulline, are independently demonstrated to have any pharmacological effects. And there is no data produced by these types of exemplifications to permit the ordinary practitioner to determine the differences in the effectiveness of L-arginine and L-citrulline if any. Therefore, examiner concludes that the instant claimed subject matter does not have sufficient support in the form of an adequate written description.

Claims **9 and 17** are objected to because of the following informalities:

In claim **9** at line 1, the term "formulated in a form of administration" is grammatically incorrect. Did applicant intend the term to read -- formulated for a form of administration -- (emphasis added)? See also claim **17** wherein the same error reoccurs.

Appropriate correction is required.

Claims **7 and 29** are rejected under 35 U.S.C. §112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim **7** fails to further limit the subject matter of the claim from which it depends because the instant stated limitation has no patentable weight in a composition claim; i.e. the instant limitation is only appropriate in a method of treatment claim.

Claim **29** improperly depends from itself.

Claims **10, 16, 18 and 25** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim **10** appears to be a -- pharmaceutical composition claim -- and therefore is incomplete for failure to specify a -- pharmaceutically acceptable carrier --. A standard format this type of claim is as follows: -- A pharmaceutical composition comprising {active ingredient(s)} in combination with a pharmaceutically acceptable carrier.-- If applicant adopts this suggestion, claim **16** become superfluous and should be cancelled. If not, then the term

"pharmaceutical carrier" in claim **16** should be amended to read -- pharmaceutically acceptable carrier -- or the like.

Claim **18** is incomplete because no specific disease condition to be treated has been specified.

In claim **25**, the term "pharmaceutical carrier" is incomplete and should be amended to read -- pharmaceutically acceptable carrier -- or the like.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam,* 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman,* 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **1-30** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim *12* of copending Application No. **10/912,717**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the active ingredients in the claimed composition are directed to substantially overlapping subject matter in view of applicant's own admission that L-arginine and L-citrulline are pharmacologically equivalent (page 4, lines 15-19 of the instant disclosure).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims **18-30** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1, 6, 8, 23-26 and 28-34*** of copending Application No. **10/207,399**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment to reduce the probability of restenosis and the active ingredients specified (Hmg-CoA reductase inhibitor and L-citrulline))are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims **1-17** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***28-37*** of copending Application No. **10/258,633**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the active ingredients in the claimed compositions are directed to substantially overlapping subject matter (an Hmg-CoA reductase inhibitor plus L-citrulline).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims **18-30** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-14*** of U. S. Patent No. **6,465,516** (PTO-892 ref. **B**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients are directed to substantially overlapping subject matter because the patented claims while being limited to administration of an Hmg-CoA reductase inhibitor, must inherently include administration of arginine and/or citrulline present *in vivo* or ingested as a normal part of the diet.

Claims **1-30** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-19*** of U. S. Patent No. **5,968,983** (PTO-1449 ref. **AH**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients (an Hmg-CoA reductase inhibitor plus L-arginine or biological equivalent including L-citrulline) are directed to substantially overlapping subject matter.

Review of the prior art presently of record, including references obtained by review of a File CAPLUS search, has not produced any reference or combination of references anticipating or rendering obvious the instant claimed subject matter. The closest prior art disclosure, other than applicant's issued patents and present applications, occurs in **Liao et al. '403** (PTO-1449 ref. **BB**) wherein the treatment of various medical conditions are claimed as a result of administration of an Hmg-CoA reductase inhibitor with dependent claims asserting the L-arginine is "a substate for Nitric Oxide Synthase," but not claiming the co-administration of L-arginine or L-citrulline with a Hmg-CoA reductase inhibitor.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < http://pair-direct.uspto.gov >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

LECrane:lec
12/14/2006

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